DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

January 4, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-26

Gretchen A. Mathers, Operating Partner
Gretchen of Schwartz
2415 Airport Way South
Seattle, Washington 98134

WARNING LETTER

Dear Ms. Mathers:

We inspected your firm located at 2415 Airport Way South, Seattle, Washington, on November 20, and December 3, 2001, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy-enclosed) listing the deviations was presented to Henry Carruth, Plant Manager, at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your ready to eat tuna sandwich to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1). You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (c) (1). Your firm's HACCP plan for tuna fish products does not list the food safety hazard of allergens. Your product contains wheat and egg, which are known allergens.

2). You must have a HACCP plan that lists an appropriate critical limit for each critical control point to comply with 21 CFR 123.6(c)(3). Your HACCP plan lists a critical limit of 45 degrees at the "tuna mix holding storage" critical control point. 45 ° F is not adequate to control the hazard of pathogen growth.

3). You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6 (c)(4). However, your firm's HACCP plan for tuna sandwiches and tuna salad lists a monitoring procedure of two times per day at the holding storage step and the finished product storage step. Twice daily monitoring is not adequate to control the hazard of pathogen growth.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Mr. Williamson at (425) 483-4976.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483